NxPCM Assessment for VIBE

Date Evaluated: July 14, 2009

Study Title: "Retention of Skeletal, Musculature, and Postural Status with a Non-invasive, Extremely Low-level Mechanical Signal: A Ground-based Evaluation of Efficacy"; VIBE: Vibrational Inhibition of Bone Erosion. Research Grant # NNJ05HA02G

Principal Investigator(s): Clinton T. Rubin, Ph.D.; Stefan Judex (Co-I); Yi-Xian Qin (Co-I)

Research Gaps

- Gap(s) associated with this study:
  - B18: Is vibration a good countermeasure and how should it be used?
- Recommended future studies or gap(s):
  - Gap B18 has been closed as a result of this study. The project recommends the evaluation of other mechanical countermeasures such as PEMF to mitigate bone loss.

NxPCM Study Summary:

A complete review of the ground-based study data was performed during the VIBE review January 10-11, 2008. The flight investigation was previously placed on hold while the efficacy of VIBE was tested in bed rest. As a result of the review the flight study was recommended for de-selection and was cancelled. The ground-based study was completed and the grant ended December 31, 2008. The final report provided by Dr. Rubin in March 2009 indicates retention of bone loss by the vibration signal, but the project does not agree based on data provided in the final report. The project requested the report to be reviewed by a NASA statistician (Dr. Robert Ploutz-Snyder) who performed a thorough analysis of the provided information. He noted several potential issues with the data as it is presented in the report and made a recommendation that all of the raw data on all of the subjects be re-analyzed by a NASA biostatistician (or local if PI chooses) to determine the magnitude of effect of the VIBE treatment. After review of the current report, the NxPCM project continues to support the recommendation for closure. The project recommends requiring the principal investigator to work with a biostatistician (NASA preferably) to revise the final report and re-submit a more detailed and complete version for evaluation.